EXHIBIT G

LEXSEE 394 MASS. 131, 135

Carole D. MacDonald & another [1] v. Ortho Pharmaceutical Corporation

1 The other plaintiff is Bruce MacDonald, Carole MacDonald's husband.

No. W-3489

Supreme Judicial Court of Massachusetts

394 Mass. 131; 475 N.E.2d 65; 1985 Mass. LEXIS 1370; CCH Prod. Liab. Rep. P10,454

May 8, 1984, Argued
February 28, 1985, Decided

PRIOR HISTORY: [***1] Worcester.

Civil action commenced in the Superior Court on February 15, 1978.

The case was tried before *William C. O'Neil, Jr.*, J.

The Supreme Judicial Court on its own initiative transferred the case from the Appeals Court.

DISPOSITION: *So ordered.*

COUNSEL: *John F. Keenan* for the plaintiffs.

Robert W. Sparks of New Jersey (*Edward P. Leibensperger* with him) for the defendant.

JUDGES: Hennessey, C.J., Liacos, Abrams, Nolan, & O'Connor, JJ. O'Connor, J., dissenting.

OPINION BY: ABRAMS

OPINION

[*132] [**66] This products liability action raises the question of the extent of a drug [***3] manufacturer's duty to warn consumers of dangers inherent in the use of oral contraceptives. The plaintiffs brought suit against the defendant, Ortho Pharmaceutical Corporation (Ortho), for injuries allegedly caused by Ortho's birth control pills, and obtained a jury verdict in their favor. The defen-

dant moved for a judgment notwithstanding the verdict. The judge concluded that the defendant did not owe a duty to warn the plaintiffs, and entered judgment for Ortho. The plaintiffs appealed. We transferred the case to this court on our own motion and reinstate the jury verdict. [2]

2 The only issues before us are issues of the drug manufacturer's liability.

We summarize the facts. In September, 1973, the plaintiff Carole D. MacDonald (MacDonald), who was twenty-six years old at the time, obtained from her gynecologist a prescription for Ortho-Novum contraceptive pills, manufactured by Ortho. As required by the then effective regulations promulgated by the United States Food and Drug Administration (FDA), [***4] the pill dispenser she received was labeled with a warning that "oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women," and that "[t]he most serious known side effect is abnormal blood clotting which can be fatal." [3] The [*133] warning also referred MacDonald [**67] to a booklet which she obtained from her gynecologist, and which was distributed by Ortho pursuant to FDA requirements. The booklet contained detailed information about the contraceptive pill, including the increased risk to pill users that vital organs such as the brain may be damaged by abnormal blood clotting. [4] The word [*134] "stroke" did not appear on the dispenser warning or in the booklet.

3 FDA regulations in effect during the time period relevant to this litigation required that the following warning be included in or with the pill dispenser:

"Do Not Take This Drug Without Your Doctor's Continued Supervision.

"The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.

"Safe use of this drug requires a careful discussion with your doctor. To assist him in providing you with the necessary information, ___(Firm name) has prepared a booklet (or other form) written in a style understandable to you as the drug user. This provides information on the effectiveness and known hazards of the drug including warnings, side effects and who should not use it. Your doctor will give you this booklet (or other form) if you ask for it and he can answer any questions you may have about the use of this drug.

"Notify your doctor if you notice any unusual physical disturbance or discomfort."

21 C.F.R. § 130.45(d)(1), 35 Fed. Reg. 9002-9003 (1970), recodified at 21 C.F.R. § 310.501(a)(4), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5354 (1975).

[***5]

4 Applicable FDA regulations required that the booklet contain "information in lay language, concerning effectiveness, contraindications, warnings, precautions, and adverse reactions," including a warning "regarding the serious side effects with special attention to thromboembolic disorders and stating the estimated morbidity and mortality in users vs. nonusers." 21 C.F.R. § 130.45(e) & (e)(3), 35 Fed. Reg. 9002, 9003 (1970), recodified at 21 C.F.R. §

310.501(a)(6) & (a)(6)(iii), 39 Fed. Reg. 11680 (1974), 40 Fed. Reg. 5353 (1975). Ortho's booklet contained the following information:

> "About blood clots
>
> "Blood clots occasionally form in the blood vessels of the legs and the pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain. It has been estimated that about one woman in 2,000 on the pill each year suffers a blood clotting disorder severe enough to require hospitalization. The estimated death rate from abnormal blood clotting in healthy women under 35 not taking the pill is 1 in 500,000; whereas for the same group taking the pill it is 1 in 66,000. For healthy women over 35 not taking the pill, the rate is 1 in 200,000 compared to 1 in 25,000 for pill users. Blood clots are about three times more likely to develop in women over the age of 34. For these reasons it is important that women who have had blood clots in the legs, lungs or brain not use oral contraceptives. Anyone using the pill who has severe leg or chest pains, coughs up blood, has difficulty breathing, sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness of an arm or leg, should call her doctor immediately and stop taking the pill."

[***6] MacDonald's prescription for Ortho-Novum pills was renewed at subsequent annual visits to her gynecologist. The prescription was filled annually. On July 24, 1976, after approximately three years of using the pills, MacDonald suffered an occlusion of a cerebral artery by a blood clot, an injury commonly referred to as a stroke. [5] The injury caused the death of approximately twenty per cent of MacDonald's brain tissue, and left her permanently disabled. She and her husband initiated an action in the Superior Court against Ortho, seeking recovery for her personal injuries and his consequential damages and loss of consortium.

5 MacDonald's hospital records refer to her injury as a "cerebral vascular accident," terminology likewise descriptive of brain damage attributable to blood clotting.

MacDonald testified that, during the time she used the pills, she was unaware that the risk of abnormal blood clotting encompassed the risk of stroke, and that she would not have used the pills had she been warned that stroke [***7] is an associated risk. [6] The case was submitted to a jury on the [**68] plaintiffs' theories that Ortho was negligent in failing to warn adequately of the dangers associated with the pills and that Ortho breached its warranty of merchantability. These two theories were treated, in effect, as a single claim of failure to warn. The jury returned a special verdict, finding no negligence or breach of warranty in the manufacture of the pills. The jury also found that Ortho adequately advised the gynecologist of the risks inherent in the pills; [7] the jury found, however, that Ortho was negligent and [*135] in breach of warranty because it failed to give MacDonald sufficient warning of such dangers. The jury further found that MacDonald's injury was caused by Ortho's pills, that the inadequacy of the warnings to MacDonald was the proximate cause of her injury, and that Ortho was liable to MacDonald and her husband. [8]

6 Subsequent to the events in this case, the FDA regulation was amended by 43 Fed. Reg. 4221 (1978), which replaced the regulation requirement of a specified warning on the pill dispenser, see note 3, *supra*, with a requirement that the dispenser contain a warning "of the serious side effects of oral contraceptives, such as thrombophlebitis, pulmonary embolism, myocardial infarction, retinal artery thrombosis, *stroke*, benign hepatic adenomas, induction of fetal abnormalities, and gallbladder disease" (emphasis added). See 21 C.F.R. § 310.501(a) (2)(iv) (1984).

[***8]

7 MacDonald stated at trial that her gynecologist had informed her only that oral contraceptives might cause bloating, and had not advised her of the increased risk of stroke associated with consumption of birth control pills. The physician was not joined as a defendant in this action, and no questions relating to any potential liability on his part are before us.

MacDonald further testified at trial that she had read both the warning on the Dialpak tablet dispenser as well as the booklet which she received from her gynecologist. See notes 3 and 4, *supra*.

8 The only issue before us concerns the scope of Ortho's duty to the plaintiffs. The defendant does not contest the damages but relies solely on its claim that it owes no duty to warn the plaintiffs directly.

After the jury verdict, the judge granted Ortho's motion for judgment notwithstanding the verdict, concluding that, because oral contraceptives are prescription drugs, a manufacturer's duty to warn the consumer is satisfied if the manufacturer gives adequate warnings to the prescribing physician, and that the manufacturer [***9] has no duty to warn the consumer directly.

The narrow issue, on appeal, is whether, as the plaintiffs contend, a manufacturer of birth control pills owes a direct duty to the consumer to warn her of the dangers inherent in the use of the pill. We conclude that such a duty exists under the law of this Commonwealth.

1. *Extent of duty to warn.* Ordinarily, "a manufacturer of a product, which the manufacturer knows or should know is dangerous by nature or is in a dangerous condition," is under a duty to give warning of those dangers to "persons who it is foreseeable will come in contact with, and consequently be endangered by, that product." *H.P. Hood & Sons* v. *Ford Motor Co.*, 370 Mass. 69, 75 (1976). The element of privity being long discarded, a manufacturer's warning to the immediate purchaser will not, as a general matter, discharge this duty. However, "there are limits to that principle." *Carter* v. *Yardley & Co.*, 319 Mass. 92, 98 (1946). Thus, "a manufacturer may be absolved from blame because of a justified reliance upon . . . a middleman." *Id.* at 99. This exception is applicable [*136] only in the limited instances in which the manufacturer's reliance [***10] on an intermediary is reasonable. See Restatement (Second) of Torts § 388 comment n (1965). In such narrowly defined circumstances, the manufacturer's immunity from liability if the consumer does not receive the warning is explicable on the grounds that the intermediary's failure to warn is a superseding cause of the consumer's injury, or, alternatively, that, because it is unreasonable in such circumstances to expect the manufacturer to communicate with the consumer, the manufacturer has no duty directly to warn the consumer. [9] See generally 1A L. Frumer & M. [**69] Friedman, Products Liability §§ 8.01, 8.03 [3] (1983 & Supp. 1984); Restatement (Second) of Torts, *supra* at § 452 comment f.

9 Ortho points out that a number of courts have reached this result in oral contraceptive cases. See, e.g., *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (applying New Hampshire law); *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (applying New York law); *Skill* v. *Martinez*, 91 F.R.D. 498, 507 (D. N.J. 1981), aff'd, 677 F.2d 368 (3d Cir. 1982); *Goodson* v. *Searle Laboratories*, 471 F. Supp. 546, 549 (D. Conn. 1978); *Dunkin* v. *Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977); *Chambers* v. *G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975), aff'd per curiam, 567 F.2d 269 (4th Cir. 1977); *Carmichael* v. *Reitz*, 17 Cal. App. 3d 958, 989 (1971); *Hamilton* v. *Hardy*, 37 Colo. App. 375, 387 (1976); *Mahr* v. *G.D. Searle & Co.*, 72 Ill. App. 3d 540, 561 (1979); *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 43 (1979); *Seley* v. *G.D. Searle & Co.*, 67 Ohio St. 2d 192, 198 (1981); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 385 (1974); *Leibowitz* v. *Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 431 (1973). See also *Terhune* v. *A.H. Robins Co.*, 90 Wash. 2d 9, 14 (1978) (intrauterine contraceptive device).

[***11] The rule in jurisdictions that have addressed the question of the extent of a manufacturer's duty to warn in cases involving prescription drugs is that the prescribing physician acts as a "learned intermediary" between the manufacturer and the patient, and "the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty." *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 386-387 (1974). Oral contraceptives, however, bear peculiar characteristics which warrant the imposition of a common law [*137] duty on the manufacturer to warn users directly of associated risks. Whereas a patient's involvement in decision making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use "the pill," as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role. [10]

10 According to the American Medical Association, "the medical profession regards the pill, in most cases, as a convenience rather than a traditional medication." Statement of American Medical Association, published in Science News, March 14, 1970, quoted in Comment, Liability of Birth Control Pill Manufacturers, 23 Hastings L.J. 1526, 1532 (1972). These distinguishing features have been recognized by legal commentators as well as by the medical profession. See Merrill, Compensation for Prescription Drug Injuries, 59 Va. L. Rev. 1, 91, 93 (1973); Comment, Liability of Birth Control Pill Manufacturers, 23 Hastings L.J. 1526, 1538-1543 (1972).

[***12] Furthermore, the physician prescribing "the pill," as a matter of course, examines the patient once before prescribing an oral contraceptive and only annually thereafter. J. Willson, E. Carrington, & W. Ledger, Obstetrics and Gynecology 184 (7th ed. 1983). D. Danforth, Obstetrics and Gynecology 267 (4th ed. 1982). T. Green, Gynecology: Essentials of Clinical Practice 593 (3d ed. 1977). At her annual checkup, the patient receives a renewal prescription for a full year's supply of the pill. [11] Thus, the patient may only seldom have the opportunity to explore her questions and concerns about the medication with the prescribing physician. Even if the physician, on those occasions, were scrupulously to remind the patient of the risks attendant on continuation of the oral contraceptive, "the patient cannot be expected to remember all of the details for a protracted period of time." 35 Fed. Reg. 9002 (1970).

11 MacDonald saw her gynecologist once in the summer of 1973, once in the summer of 1974, and once in August of 1975. At each appointment, she received a prescription for birth control pills. Thus, eleven months had elapsed between her last gynecological checkup and her stroke in July, 1976.

[***13] Last, the birth control pill is specifically subject to extensive Federal regulation. The FDA has promulgated regulations designed to ensure that the choice of "the pill" as a contraceptive [*138] method is informed by comprehensible warnings of potential side effects. [12] See notes 3 and 4, *supra*. These regulations, and subsequent amendments, have their basis in the FDA commissioner's finding, after hearings, that "[b]ecause oral contraceptives are ordinarily taken electively by healthy women who have available to them alternative methods [**70] of treatment, and because of the relatively high incidence of serious illnesses associated with their use, . . . users of these drugs should, without exception, be furnished with written information telling them of the drug's benefits and risks." 43 Fed. Reg. 4215 (1978). The FDA also found that the facts necessary to informed decisions by women as to use of oral contraceptives are "too complex to expect the patient to remember everything told her by the physician," and that, in the absence of direct written warnings, many potential users of "the pill" do not receive the needed information "in an organized, comprehensive, [***14] understandable, and handy-for-future-reference form." 35 Fed. Reg. 9002 (1970).

12 See 21 C.F.R. § 130.45(a), 35 Fed. Reg. 9002 (1970) (oral contraceptives "are used for long periods of time by large numbers of women who, for the most part, are healthy and take them as a matter of choice for prophylaxis against pregnancy, in full knowledge of other means of contraception"); 43 Fed. Reg. 4215 (1978).

The oral contraceptive thus stands apart from other prescription drugs in light of the heightened participation of patients in decisions relating to use of "the pill"; the substantial risks affiliated with the product's use; the feasibility of direct warnings by the manufacturer to the user; the limited participation of the physician (annual prescriptions); and the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at [***15] subsequent points when alternative methods may be considered. We conclude that the manufacturer of oral contraceptives is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user. Thus, the [*139] manufacturer's duty is to provide to the consumer written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information of concern to the consumer. [13]

13 This opinion does not diminish the prescribing physician's duty to "disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to" take "the pill." *Harnish* v. *Children's Hosp. Medical Center*, 387 Mass. 152, 155 (1982).

[***16] 2. *Adequacy of the warning*. Because we reject the judge's conclusion that Ortho had no duty to warn MacDonald, we turn to Ortho's separate argument, not reached by the judge, that the evidence was insufficient to warrant the jury's finding that Ortho's warnings to MacDonald were

inadequate. Ortho contends initially that its warnings complied with FDA labeling requirements, and that those requirements preempt or define the bounds of the common law duty to warn. We disagree. The regulatory history of the FDA requirements belies any objective to cloak them with preemptive effect. In response to concerns raised by drug manufacturers that warnings required and drafted by the FDA might be deemed inadequate by juries, the FDA commissioner specifically noted that the boundaries of civil tort liability for failure to warn are controlled by applicable State law. 43 Fed. Reg. 4214 (1978). Although the common law duty we today recognize is to a large degree coextensive with the regulatory duties imposed by the FDA, we are persuaded that, in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not [***17] adequately apprise oral contraceptive users of inherent risks, the manufacturer should not be shielded from liability by such compliance. See *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Skill* v. *Martinez*, 91 F.R.D. 498, 508 (D.N.J. 1981); *Stevens* v. *Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 397-398 (1974). Cf. *Hubbard-Hall Chem. Co.* v. *Silverman*, 340 F.2d 402, 405 [*140] (1st Cir. 1965); *Ferebee* v. *Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C. 1982). See generally 1A L. Frumer & M. Friedman, Products Liability § 8.07[1] (1983). Thus, compliance [**71] with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue, just as violation of FDA requirements is evidence, but not conclusive evidence, of negligence. See *Deignan* v. *Lubarsky*, 318 Mass. 661, 664 (1945). See also *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 965 (E.D. Wis. 1981). We therefore concur with the plaintiffs' argument that even if the conclusion that Ortho complied with FDA requirements were inescapable, [***18] an issue we need not decide, the jury nonetheless could have found that the lack of a reference to "stroke" breached Ortho's common law duty to warn.

The common law duty to warn, like the analogous FDA "lay language" requirement, necessitates a warning "comprehensible to the average user and . . . convey[ing] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person." *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 49 (1979), quoting *Spruill* v. *Boyle-Midway, Inc.*, 308 F.2d 79, 85 (4th Cir. 1962). Whether a particular warning measures up to this standard is almost always an issue to be resolved by a jury; few questions are "more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person." *Ferebee* v. *Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C. 1982). See *Hayes* v. *Ariens Co.*, 391 Mass. 407, 409-410 (1984). A court may, as a matter of law, determine "whether the defendant has conformed to that standard, in any case in which the jury may not reasonably come to a different conclusion," Restatement (Second) of Torts § 328B [***19] (d) and comment g (1965), but judicial intrusion into jury decision making in negligence cases is exceedingly rare. See *Croley* v. *Matson Navigation Co.*, 434 F.2d 73, 75 (5th Cir. 1970). Further, we must view the evidence in the light most favorable to the plaintiffs. *Uloth* v. *City Tank Corp.*, 376 Mass. 874, 876 (1978). The test is whether "anywhere in the evidence, from whatever source derived, any combination of [*141] circumstances could be found from which a reasonable inference could be drawn in favor of the plaintiff." *Poirier* v. *Plymouth*, 374 Mass. 206, 212 (1978), quoting *Raunela* v. *Hertz Corp.*, 361 Mass. 341, 343 (1972). Accord *Michnik-Zilberman* v. *Gordon's Liquor, Inc.*, 390 Mass. 6, 7 n.1 (1983).

Ortho argues that reasonable minds could not differ as to whether MacDonald was adequately informed of the risk of the injury she sustained by Ortho's warning that the oral contraceptives could cause "abnormal blood clotting which can be fatal" and further warning of the incremental likeli-

hood of hospitalization or death due to blood clotting in "vital organs, such as the brain." We disagree. "The fact finder may find a warning to be [***20] unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is conveyed. . . . The adequacy of such warnings is measured not only by what is stated, but also by the manner in which it is stated. A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk. A warning may be found to be unreasonable in that it was unduly delayed, reluctant in tone or lacking in a sense of urgency." *Seley* v. *G.D. Searle Co.*, 67 Ohio St. 2d 192, 198 (1981). We cannot say that this jury's decision that the warning was inadequate is so unreasonable as to require the opposite conclusion as a matter of law. [14] The jury may well have concluded, in light of their common experience and MacDonald's testimony, that the absence of a reference to "stroke" in the warning unduly minimized the warning's impact or failed to make the nature of the risk reasonably [**72] comprehensible to the average consumer. Similarly, the jury may have concluded that there are fates worse than death, such as the permanent disablement suffered by MacDonald, [***21] and that the mention of the risk of death did not, therefore, suffice to apprise an average consumer of the material risks of oral contraceptive use. Cf. *Hubbard-Hall Chem. Co.* v. *Silverman*, 340 F.2d 402, 405 (1st Cir. 1965).

14 See Weinberger, Collateral Estoppel and the Mass Produced Product: A Proposal, 15 New Eng. L. Rev. 1, 36-38 (1980).

[*142] Ortho's argument that, as a matter of law, there was insufficient evidence that MacDonald's injury was proximately caused by a deficiency in the warnings is substantially similar to its argument on the issue of the adequacy of the warnings, and is likewise unavailing. Relying on *Harnish* v. *Children's Hosp. Medical Center*, 387 Mass. 152 (1982), for the proposition that MacDonald had the burden of proving causation by showing that "had the proper information been provided neither [s]he nor a reasonable person in similar circumstances" would have accepted Ortho's pills as a contraceptive method, *id.* at 158, Ortho argues that "[t]here was [***22] no evidence that a reasonable person, having been informed of the risk of death by abnormal blood clotting and having chosen to assume the risk, would have acted differently if informed of the risk of 'stroke.'" The jury were free, however, to credit MacDonald's testimony that she would not have used the pills had she been advised of the danger of "stroke," and to infer that an explicit reference to the risk of stroke might tip the balance in a reasonable person's choice of a contraceptive method. Ortho also asserts that evidence that MacDonald did not ask her gynecologist for an explanation of the meaning of "abnormal blood clotting" or inform him of two episodes of numbness in her hand subsequent to her initiation of oral contraceptive use indicates that MacDonald was not disposed to heed Ortho's warnings, and, consequently, that the evidence did not permit an inference that a different warning by Ortho would have affected MacDonald's decision to use Ortho's pills. These arguments raise the issue of the plaintiff Carole MacDonald's comparative negligence. That issue was not raised below and thus is not before us. *Kagan* v. *Levenson*, 334 Mass. 100, 106 (1956).

We reverse [***23] the judgment, which the judge ordered notwithstanding the verdict, and remand the case to the Superior Court for the entry of judgment for the plaintiffs.

So ordered.

DISSENT BY: O'CONNOR

DISSENT

O'Connor, J. (dissenting).

The court reverses the judgment below and holds Ortho Pharmaceutical Corporation (Ortho) [*143] liable to Carole and Bruce MacDonald even though the jury found that Ortho adequately informed Carole MacDonald's physician of the risks associated with the use of its contraceptive pills, and regardless of whether Ortho complied with the applicable Federal Food and Drug Administration (FDA) regulations governing the provision of printed information to users of oral contraceptives. I would hold that, as a matter of law, by adequately informing physicians of the risks associated with its product and by complying with applicable FDA regulations, a contraceptive pill manufacturer fulfils the duty to warn that it owes consumers. Therefore, because the jury found that Ortho adequately warned Carole MacDonald's physician of the risks associated with its contraceptive pills and because the MacDonalds presented no evidence that Ortho failed to comply with FDA regulations, [***24] I would affirm the judgment for Ortho.

In order to fulfil its duty to warn consumers of risks associated with its product, a manufacturer of a nonprescription ("over-the-counter") drug must place on the drug's package printed warnings. That duty "derives from the basic marketing predicate of the over-the-counter drug industry, namely, that nonprescription drugs are purchased by consumers for the purpose of self-medication *typically without any intended or actual intervention by a physician." Torsiello* v. *Whitehall Laboratories*, 165 N.J. Super. 311, 322 (1979) (emphasis added). In contradistinction, [**73] a manufacturer of a prescription drug fulfils its duty to warn a consumer by adequately informing the consumer's physician -- a "learned intermediary between the purchaser and the manufacturer" -- of the drug's associated risks. *Sterling Drug, Inc.* v. *Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). That rule results from the fact that, by definition, before a consumer uses a prescription drug, that consumer must have some interaction with a doctor. See 21 U.S.C. § 353(b)(1) (1982). [1] In cases involving manufacturers of contraceptive [*144] pills, every court [***25] but one has adhered to the "prescription drug" rule. See *Hamilton* v. *Hardy*, 37 Colo. App. 375, 387 (1976); *Mahr* v. *G.D. Searle & Co.*, 72 Ill. App. 3d 540, 561 (1979); *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 43 (1979); *Cobb* v. *Syntex Laboratories, Inc.*, 444 So.2d 203, 205 (La. App. 1983); *Seley* v. *G.D. Searle & Co.*, 67 Ohio St. 2d 192, 202-203 (1981); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 385 (1974); *Leibowitz* v. *Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 431 (1973); *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981); *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Goodson* v. *Searle Laboratories*, 471 F. Supp. 546, 548 (D. Conn. 1978); *Dunkin* v. *Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (D. Tenn. 1977); *Chambers* v. *G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975); *Skill* v. *Martinez*, 91 F.R.D. 498, 507 (D.N.J. 1981). See also *Carmichael* v. *Reitz*, 17 Cal. App. 3d 958, 989 (1971) (oral contraceptive pills used to treat woman for endometriosis and to aid her to become pregnant); *Terhune* [***26] v. *A.H. Robins Co.*, 90 Wash. 2d 9, 13 (1978) (intrauterine contraceptive device). But see *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963, amended by order, 532 F. Supp. 211 (D. Wis. 1981). The one court that went beyond the prescription drug rule, see *Lukaszewicz* v. *Ortho Pharmaceutical Corp., supra*, imposed on Ortho the duty to adequately inform physicians of the contraceptive pill's risks and to comply with applicable FDA regulations. 532 F. Supp. at 213. To my knowledge, no other court has embraced the rule laid down today by the court.

1 Section 353(b)(1) provides: "A drug intended for use by man which -- (A) is a habit-forming drug to which section 352(d) of this title applies; or (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

[***27] [*145] Before prescribing any drug, whether on the doctor's initiative or at the patient's request, the doctor must exercise professional judgment as to the medical propriety of that patient's taking that drug and, in exercising that judgment, the doctor must conform to the standards of good medical practice laid down in *Brune* v. *Belinkoff*, 354 Mass. 102, 109 (1968). Furthermore, this court has held that a doctor must "disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient whether to undergo a proposed procedure." *Harnish* v. *Children's Hosp. Medical Center*, 387 Mass. 152, 155 (1982). That rule applies when a physician prescribes a drug just as it does when a physician performs any other medical procedure. "Materiality may be said to be the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed [**74] risk or risks in deciding whether to [use the drug]." *Id.* at 156, quoting from *Wilkinson* v. *Vesey*, 110 R.I. 606, 627 (1972). "Appropriate [***28] information may include the nature . . . and probability of risks involved, the benefits to be reasonably expected, the inability of the physician to predict results, . . . , and the available alternatives, including their risks and benefits." *Harnish, supra* at 156.

Unless doctors have current, accurate, and complete information about a drug's risks, they cannot properly perform their vital role. Therefore, courts have imposed on drug manufacturers the duty to provide doctors with that information. See, e.g., *Brochu* v. *Ortho Pharmaceutical Corp., supra* at 657-659. A drug manufacturer who fails properly to fulfil that duty must respond in damages to a patient who suffers an injury as a result. See, e.g., *McEwen* v. *Ortho Pharmaceutical Corp., supra* at 386-387.

I believe that the "prescription drug" rule, combined with the *Harnish* rule, most fairly and efficiently allocates among drug manufacturers, physicians, and drug users, the risks and responsibilities involved with the use of prescription drugs. Furthermore, I believe that those rules best ensure that a prescription drug user will receive in the most effective manner [*146] the information that [***29] she needs to make an informed decision as to whether to use the drug. The rules place on drug manufacturers the duty to gather, compile, and provide to doctors data regarding the use of their drugs, tasks for which the manufacturers are best suited, and the rules place on doctors the burden of conveying those data to their patients in a useful and understandable manner, a task for which doctors are best suited. Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug. Manufacturers are not in position to give adequate advice di-

rectly to those consumers whose medical histories and physical conditions, perhaps unknown to the consumers, make them peculiarly susceptible to risk. Prescription drugs -- including oral contraceptives -- differ from other products because their dangers vary widely depending on characteristics of individual consumers. Exposing a prescription drug manufacturer to liability based on a jury's determination that, despite adequately informing physicians of the drug's risks and complying with FDA regulations, the [***30] manufacturer failed reasonably to warn a particular plaintiff-consumer of individualized risks is not essential to reasonable consumer protection and places an unfair burden on prescription drug manufacturers.

Even though the court recognizes the universal application of the "prescription drug" rule, it states that "[o]ral contraceptives . . . bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks." *Ante* at 136-137. The court attempts to distinguish contraceptive pills from other prescription drugs by comparing the relative involvement of doctor and patient in the prescribing process. "Whereas a patient's involvement in decision making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent," the court asserts, "the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use 'the pill,' as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive [*147] role." *Ante* at 137. In making that statement, the court not only assumes facts not [***31] established on the record but also disregards the mandate of *Harnish* v. *Children's Hosp. Medical Center, supra*.

While I would choose the "prescription drug" rule over the rule announced today by the court, I recognize that the FDA has promulgated regulations governing the provision of printed information to users of oral contraceptives. I would not consider the imposition of tort liability for failure to comply with those regulations, designed to further consumer protection, unfair nor unduly burdensome to contraceptive pill manufacturers. [**75] However, in my view, the evidence in this case would not support a finding that Ortho failed to comply with those regulations. The FDA required Ortho to place on every oral contraceptive pill dispenser a warning stating that the "most serious known side effect [of the oral contraceptive pill] is abnormal blood clotting which can be fatal." 21 C.F.R. § 130.45(d)(1), 35 Fed. Reg. 9002-9003 (1970). Ortho complied in every way with that requirement. The FDA also required that Ortho make available to physicians for patients who requested it "information in lay language, concerning effectiveness, contraindications, warnings, [***32] precautions, and adverse reactions." 21 C.F.R. § 130.45(e), 35 Fed. Reg. 9003 (1970). Ortho provided Carole MacDonald's physician with a booklet that stated: "Blood clots occasionally form in the blood vessels of the legs and pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain." MacDonald's physician gave Ortho's booklet to MacDonald. The court finds it unnecessary to decide whether Ortho complied with FDA's "lay language" requirement, *ante* at 140-141, but I do not believe that any rational trier of fact could have concluded that Ortho failed to comply with the regulation.

Furthermore, even if there be a common law duty necessitating a direct warning to the consumer with respect to the "nature and extent of the danger" of contraceptive pills, as the court declares, the MacDonalds presented no evidence that Ortho failed to fulfil that duty. The court states only that the jury [*148] "could have found that the lack of reference to 'stroke' breached Ortho's common law duty to warn." *Ante* at 140. Surely, the statement in Ortho's booklet that the contraceptive [***33] pill could cause life threatening blood clots to form in the brain, even though it did not contain the word "stroke," satisfied the court's requirement that Ortho provide "written warnings

conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects." *Ante* at 139. I would affirm the judgment for Ortho.